IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT DIABETES CARE, INC., a Delaware corporation, Plaintiff, v. DEXCOM, INC., a Delaware corporation, Defendant.	)	C.A. No. 05-590 (GMS) **REDACTED PUBLIC VERSION**

ABBOTT'S ANSWERING BRIEF IN OPPOSITION TO DEXCOM'S MOTION TO STAY PENDING REEXAMINATION OF THE PATENTS IN SUIT

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INTRODUCTION

The Court should deny DexCom's motion to stay, which would gravely prejudice Abbott Diabetes Care, Inc. ("Abbott"). Under the law, courts should deny a stay when it "would unduly prejudice or present a clear tactical disadvantage to the non-moving party." *See, e.g., St. Clair Intellectual Property Consultants Inc. v. Sony Corp.*, No. 01-557-JJF, slip op. at 2 (D. Del. Jan. 30, 2003).

That is exactly the situation here. Granting a stay would extinguish Abbott's ability even to request preliminary injunctive relief to stop DexCom's imminent product launch. Patents, however, give their owners the right to market exclusivity and the consequent right to protect that exclusivity through a request for a preliminary injunction. Infringers cannot unilaterally thwart that right without a hearing simply by requesting a discretionary stay. DexCom has failed to cite a single case supporting that fundamentally unfair notion.

If DexCom's position had any merit, preliminary injunctions would be virtually impossible to obtain in patent cases. To avoid even a hearing on a preliminary injunction, every infringer would simply file a reexamination request with the PTO and then, based on that filing alone, ask the district court to stay the litigation. The infringer would never have to confront the traditional criteria courts consider when granting preliminary injunctions, including irreparable harm to the patent owner and the likelihood of success on the merits. The law simply does not permit infringers to so easily trample on patent rights.

Here, granting a stay before addressing a preliminary injunction motion would eliminate, without a hearing on the merits, most of the value of four patents owned

by Abbott. DexCom is on the verge of launching a glucose monitoring device that infringes Abbott's patents. Abbott and its predecessor, however, spent over a decade and hundreds of millions of dollars inventing and developing the patented technology. Abbott is now only about ten months away from launching a commercial version of its patented inventions. That product, the Freestyle Navigator™, is a pioneering product that promises to revolutionize glucose-monitoring for diabetes patients.

To attempt to rush an infringing product to market before Abbott, DexCom has relied on a plethora of maneuvers, including pushing forward with a product with inferior accuracy, seeking a less-rigorous, but faster level of approval from the FDA, and attempting to delay the progress of this case. DexCom's strategy is clear. It wants to be the first to market its infringing product, capture as much market share as possible, realize substantial profits, irreparably damage the market for Abbott's product, and deal with the consequences of its infringement as far in the future as possible.

DexCom's latest maneuver is this motion to stay, which is based on reexamination requests filed only recently with the PTO on January 25, 2006 and February 1, 2006. In these requests, DexCom argues that certain prior art, much of which the PTO already considered, renders invalid a total of 163 claims in four different patents. For numerous claims, DexCom's arguments are nothing more than run-of-the-mill obviousness arguments, which are based on prior art that is plainly missing some of Abbott's main innovations. Even though the PTO has responded to only two of four requests, DexCom asks the Court to stay this litigation for potentially years while the PTO considers those requests as a "prudential matter" in order to "streamline" this litigation.

But the legal issue now before the Court is only whether DexCom should be allowed to launch before the infringement and validity issues are addressed. This determination will require a preliminary injunction hearing, not protracted discovery and a full trial on the merits. Granting a stay at this stage of the litigation would be grossly premature, would deprive Abbott of its right to be heard on its request for injunctive relief, would dramatically alter the status quo by allowing DexCom to launch its infringing product, and would substantially and irreparably harm Abbott. The Court should deny the motion.

FACTUAL BACKGROUND

A. Abbott's Patented Technology

DexCom is infringing at least four Abbott Patents[1] that relate to a new way of testing glucose levels for patients suffering from diabetes. Right now, patients monitor their glucose levels by pricking their fingers to draw blood several times a day – a painful, imperfect, and inconvenient process that merely provides a snapshot of glucose levels at a particular instant in time. (Declaration of Timothy Goodnow at ¶ 5).

Abbott's patented inventions, in contrast, involve implanting a glucose sensor into the patient's body and then remotely monitoring radio signals from the sensor for its multi-day life. (*Id.* at ¶ 6). This gives the patients virtually continuous feedback about their glucose levels, including current glucose levels and trend information about changing levels. (*Id.*). Abbott's technology also includes an alarm feature, which alerts

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[1] The current Abbott patents in suit are U.S. Pat. Nos. 6,175,752 (the "'752 patent"), 6,284,478 (the "'478 patent"), 6,329,161 (the "'161 patent") and 6,565,509 (the "'509 patent").

the patient to possible dangerous trends, such as rapid blood glucose descents that may lead to hypoglycemia or assents that may lead to hyperglycemia. (*Id.*).

Before Abbott came along, the concept of remotely monitoring glucose levels with implantable sensors and radio signals was little more than science fiction. Abbott and its predecessor, Therasense, (collectively "Abbott") were the first to make those concepts a practical reality that could benefit patients in their everyday lives. Indeed, the prior art includes a number of inefficient and unworkable devices that never went anywhere. Abbott overcame all the technical barriers and came up with a way of making a functional and efficient remote glucose monitoring system. (*Id.* at ¶ 4).

The work leading to Abbott's patents began over a decade ago in the early 1990's (*id.* at ¶ 7) – long before DexCom was even formed in 1999. After spending hundreds of millions of dollars, Abbott has now made remote-monitoring a reality. (*Id.*). Freestyle Navigator™, Abbott's embodiment of its patents, is expected to obtain FDA approval within about ten months. (*Id.* at ¶ 8). Abbott is seeking replacement approval for its product, which means that patients who use Abbott's product will no longer have to prick their fingers several times a day to test their glucose levels.[2] (*Id.* at ¶ 8).

B. DexCom's Unlicensed Use Of Abbott's Patented Technology

As Abbott expects discovery to confirm, DexCom initially had been working on a long-term sensor system where the sensor would be implanted for months or years – a technology that is not yet ready for marketing. It was only after DexCom learned about Abbott's ground-breaking work on short-term, multi-day sensors that it

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[2] Occasional finger pricking would be necessary only for calibration purposes. (See Goodnow Decl. at ¶ 8).

shifted its focus to copying Abbott's concept. (*See Id.* at ¶¶ 9-10). DexCom is now seeking FDA approval to market a multi-day sensor that has the precise same product configuration that Abbott has patented. (*Id.* at ¶ 10). DexCom's infringing product, the STS™ Continuous Glucose Monitoring System, would directly compete with Abbott's product. (*Id.*).

Unlike Abbott's product, however, DexCom is seeking adjunct approval for its product, which means that DexCom's product will simply be a back-up system. (*Id.* at ¶ 11). Patients using DexCom's product will still have to rely on finger-prick tests as the primary source of reliable glucose monitoring – a fact that will leave the market with the impression that glucose sensor technology is not sufficiently accurate to replace finger sticking. (*Id.* at ¶ 11). Indeed, a report by the New England Healthcare Institute has described designation as a replacement therapy as "critical" to the successful adoption of continuous glucose monitoring therapy. (*Id.* at ¶ 7). DexCom is apparently seeking this lower-level and more easily-obtained approval to attempt to leap-frog Abbott by launching its product before Abbott's launch.

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C. DexCom's Imminent Launch Plans

DexCom has filed its reexamination requests with the PTO only shortly before it expects its product will be approved for commercial launch, while at the same time DexCom has attempted to prevent disclosure in the litigation of information about how close its product really is to launch. This, in turn, has enabled to DexCom to file a stay motion before Abbott was in a position to seek a preliminary injunction. But there is now no question that DexCom's launch is imminent, as confirmed by the fact that it already has a large portion of its sales force in place for that launch. (*See, e.g.*, Ex. 2 at pp. 2, 7, Tr. of 2/27/06 Conf. Call with Investors).

At the scheduling hearing before this Court on February 23, 2006, DexCom's counsel stated that DexCom is "r*ight in the middle* of the FDA process," and there "remains a *material likelihood* that we will be asked to modify that product." (Ex.

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[3] Medtronic, Inc. manufactures a product called the Guardian RT, which has only been launched in selected cities. The Guardian RT system utilizes a glucose sensor that is inserted under the patients' skin and measures glucose levels of interstitial fluid up to every five minutes. The Guardian RT, however, has a different configuration than the Navigator and the STS system, in that the transmitter that relays glucose information to the portable receiver is connected to the glucose sensor by a wire. Because the wire can snag on clothing and is not convenient for users engaged in physical activity, the Guardian RT's configuration is less desirable than the configurations of the FreeStyle Navigator and the DexCom STS. The FDA approved the Guardian RT as an adjunct therapy for measuring glucose levels in September 2005. (Bratic Decl. at ¶ 6).

1[4] at p. 10:6-8 (emphasis added)). Those statements are not accurate. Only days later during an earnings conference call on February 27, 2006, DexCom's CEO publicly stated that they "hope for a decision from the FDA regarding the approvability of our PMA for the STS by early Q2," which is only weeks away in April 2006. (Ex. 2 at p. 1).

At the Court's scheduling hearing, DexCom's counsel also stated that there is "significant likelihood" the FDA will require an extra step of regulatory review called "panel review" that could substantially delay DexCom's approval:

> *If it goes to panel review, then we would be lucky to have a product anytime in 2006.* Thus, again, the reason – and I apologize, Your Honor, I did not mean any offense to the Court – it just seemed impossible to me, given still, the *significant likelihood that we will go to a panel review*, that I could honestly state to your Court when we would be prepared to make disclosures and to agree to a schedule.

(Ex. 1 at p. 26:18-20 (emphasis added)). Again, that is not accurate. According to its own published guidance, the FDA advises applicants about the need for a panel review at a comprehensive meeting called the "100-day meeting,"[5] which DexCom had eight months ago in July 2005. Moreover, during the earnings conference call that occurred days after the Court's scheduling conference, DexCom's CEO specifically stated that we "have *not* been notified about a need for us to go to panel for this device." (Ex. 2 at p. 8 (emphasis added)).

Finally, DexCom's counsel stated to this Court that at the very earliest, DexCom would be getting a mere "approvable" letter in a "month or two," which would

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[4] The exhibits to this brief are filed in an appendix of exhibits.

[5] Guidance on PMA Interactive Procedures for Day-100 Meetings and Subsequent Deficiencies for Use by CDRH and Industry, published February 19, 1998. (Ex. 3 at p. 2).

then require another "month or two" of negotiation with the FDA before final approval and a commercial launch. (Ex. 1 at p. 26:1 - 28:2). This is not consistent with FDA regulations or practice. While it is possible that DexCom will receive an "approvable" letter, the FDA often issues final "approval" without an intermediate "approvable" decision. *See* 21 CFR § 814.44(e) (2005). And there is certainly nothing requiring a minimum of a 30-day interval between an "approvable" letter and a final "approval." *Id.*

D. DexCom's Reexamination Request

At the same time it is actively obscuring the likelihood of an imminent launch, DexCom has asked the PTO to reexamine all of Abbott's patents. The reality is that it takes very little for an infringer to initiate a reexamination, and DexCom is taking full advantage of that low threshold to attempt to stall this litigation through its stay motion.

To raise the "substantial question" required for reexamination, the Patent Office makes clear that "it is only necessary . . . that a reasonable examiner would consider the teaching [of the prior art cited in the infringer's petition] to be important in deciding whether or not the claim is patentable," which means it does not matter whether the prior art is less relevant than the art the PTO already considered and, in fact, it is "not necessary" for the infringer to even "establish a prima facie case of unpatentability." (Ex. 4 at pp. 5-6, Ex Parte Reexamination Comm. from PTO). Moreover, the question the infringer presents is considered "new" – even if the new art is less relevant than the prior art already considered and, indeed, even if the infringer cites no new art – as long as the very "same question of patentability . . . has not been decided in a previous examination of the patent." (Ex. 4 at p. 6). Given the low threshold for reexamination, the Patent

Office grants 90% of all reexamination requests. (*See* Ex. F to DexCom's Opening Brief).

Here, DexCom is attempting to take advantage of those statistics through its stay motion. In reality, Abbott's patents were thoroughly examined before issuance. The Patent Office considered literally hundreds of references. (*See* Exs. 5–8, a list of cites to prior art on first seven pages of each Patent). The Patent Office issued numerous office actions testing and probing the most relevant prior art.

Despite that, DexCom has chosen to seek reexamination on 163 claims in all four patents, which indicates that it is using the reexamination process as a stalling tactic. Indeed, DexCom's petition urges the examiner to construe the claims "as broadly as their terms reasonably allow," which they concede is "*different*" from the standard used by the federal courts, which are charged with *correctly* construing the claim rather than adopting the broadest possible interpretation. (Ex. 9 at pp. 5-6, DexCom's Req. for Reexamination of U.S. Pat. No. '509). And, in fact, DexCom relies on overly-broad claim constructions that no court should adopt, including, for instance, arguing that the term "electrochemical sensor" includes a separate cable attached to the sensor's electrodes even though the cable is clearly not part of the sensor itself. (Ex. 9 at pp. 13-14).

With respect to many of the challenged claims, DexCom has not even mustered an anticipation argument – despite aggressively misinterpreting the claims – and instead has asserted garden-variety obviousness arguments. Of the 163 claims that it did petition for reexamination, DexCom asserts only run-of-the-mill obviousness arguments for the following claims: (1) '752 Patent: 2-12, 14-35, 38-40, 42-45, 49-51,

53, 54, 58-65, 74-86, 88-90, and 92-94; (2) '509 Patent: 3-4, 8, 13, 18, 35; (3) '161 Patent: 34-43, 45-48; and (4) the 478 Patent: 18-20. Moreover, DexCom's reexamination requests for the '509 and the '752 patents are based on 17 miscellaneous references – many of which were already before the PTO – and none of which disclose one of the central components of the claimed invention that made it such an innovative solution to a long-felt problem. (Ex. 9 at pp. 2-4; Ex. 10 at pp. 2-5, Req. for Re-examination of U.S. Pat. No. '752). That component is the use of a "sensor control unit" with a radio transmitter designed to be placed on the skin and receive and electrically connect to the electrochemical sensor, which sticks partially out of the skin. (*See, e.g.*, Ex. 8 at claim 1, Ex. 5 at claim 1). The only way that DexCom is able to argue that the prior art discloses any such configuration is by actively misinterpreting the claims, which it virtually admits by stressing that the examiner should interpret the claims *more broadly* than how a court would interpret them. (*See* Ex. 9 at p. 5; Ex. 10 at pp. 5-6).

With respect to the '161 and 478 patents, DexCom is relying primarily on prior art that the PTO already considered when first issuing the patents. This art – Sakakida, Wilkins, Johnson, Wilson '407 patent, Sternberg, and Wilson *Clinical Chemistry* – was all considered during the original examinations of the '161 and the '478 patents. (*Compare* Ex. 11 at pp. 2-3 and Ex. 12 at p. 2, Req. of Reexamination of U.S. Pat. Nos. '161 and '478 respectively *with* Ex. 7 and Ex. 6, *U.S. Pat. Nos. '161 and '478* respectively). DexCom relies on two other new references, but only in a peripheral way for a small subset of the 74 claims at issue. (*Id.)*

The bottom line is that – with an inferior product and lower-level FDA labeling – DexCom is attempting to misuse the reexamination process to leapfrog Abbott

with an earlier launch in direct violation of Abbott's patents. In fact, DexCom has stated publicly that it wants to launch "first" and that it expects to do so before Abbott early in the second quarter of 2006. (Ex. 2 at p. 11).

ARGUMENT

DexCom cannot meet its burden of establishing that this litigation should be stayed, particularly not before a preliminary injunction hearing. It is well-settled law that "[a] court is under no obligation to delay its own proceedings by yielding to ongoing PTO patent reexaminations, regardless of their relevancy to infringement claims which the court must analyze." *NTP, Inc. v. Research In Motion, Ltd.*, 397 F. Supp. 2d 785, 787 (E.D. Va. 2005). Rather, "[t]he court is not required to stay judicial resolution in view of the [PTO] reexaminations". *Viskase Corp. v. Am. Nat'l Can Co.*, 261 F.3d 1316, 1328 (Fed. Cir. 2001). Freely granting a stay every time an infringer filed a reexamination request would not promote the efficient and timely resolution of patent cases, but would invite parties to unilaterally derail timely patent case resolution by seeking reexamination. *Sovereign Software LLC v. Amazon.Com, Inc.*, 356 F. Supp. 2d 660, 662-63 (E.D. Tex. 2005).

In determining whether a stay is appropriate, a court should be guided by the following factors: "(1) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (2) whether a stay will simplify the issues in question and trial of the case; and (3) whether discovery is complete and whether a trial date has been set." *See, e.g., St. Clair Intellectual Property Consultants Inc. v. Sony Corp.*, No. 01-557-JJF, slip op. at 2 (D. Del. Jan. 30, 2003); *Xerox Corp. v. 3 Comm. Corp.*, 69 F. Supp. 2d 404, 406 (W.D.N.Y. 1999) (denying a motion to stay despite the

fact that the patents-in-suit were accepted for reexamination). These factors weigh against a stay.

I. A STAY WOULD IRREPARABLY HARM ABBOTT WHILE PROVIDING AN UNFAIR TACTICAL ADVANTAGE TO DEXCOM

Delaware courts have noted that "in balancing the[] factors, courts must be particularly mindful of the consequences of the stay on other parties." *Cognex Corp. v. National Instruments Corp.*, 2001 WL 34368283, at *1 (D. Del. June 29, 2001). In doing so, the Court must evaluate whether "there is even a fair possibility that the stay would work damage on another party." *Dentsply International, Inc. v. Kerr Manufacturing Co.*, 734 F. Supp. 656, 658 (D. Del. 1990) (internal citations omitted).

Here, a stay would gravely damage Abbott. Contrary to its statements, DexCom's motion is not intended to conserve judicial resources, to save the parties time and money, or to create a more orderly means of resolving the issues in dispute. Rather, DexCom is seeking a stay as a device to help attempt to launch its product before this Court considers Abbott's motion for a preliminary injunction. Under these circumstances, Abbott would be both unduly prejudiced and placed at a tactical disadvantage by a stay.

A. Abbott Would Be Unduly Prejudiced By A Stay

The imposition of a stay would unduly prejudice Abbott, which is the first factor in the stay analysis counseling against imposing a stay. Most importantly, a stay would divest Abbott of its right to seek injunctive relief when DexCom's product likely will receive approval within the next several months, while allowing DexCom to unfairly reap the huge rewards of being the first to launch.

It is beyond dispute that Abbott would be irreparably harmed by losing its right to have this Court consider the merits of its request for injunctive relief. A stay would not only deprive Abbott of this significant legal right, but would also allow DexCom to irreparably damage Abbott's market position, diminish the exclusivity of Abbott's patented technology, hurt Abbott's goodwill and long-term customer relationships, and cause Abbott to irreplaceably lose sales when it launches its own product.

The Federal Circuit has recognized that the threat of launching an infringing product can irreparably harm a patentee. For instance, in *Oakley Inc. v. Sunglass Hut Int'l.*, the district court held that defendant's anticipated release of a "huge number of allegedly infringing models" created a "likelihood of erosion to [plaintiff's] market presence and its goodwill associated with its patented [product]." No. SA CV 01-1065 AHS(MLGx), 2001 U.S. Dist. LEXIS 23572 at *76 (C.D. Cal. Dec. 7, 2001). *See also, Purdue Pharma. L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1368 (Fed. Cir. 2001) (upholding district court's finding of irreparable harm because of expert testimony regarding price erosion and loss of market position); *PPG Indus., Inc. v. Guardian Indus., Corp.*, 75 F.3d 1558, 1566-67 (Fed. Cir. 1996) (affirming grant of preliminary injunction based, in part, on finding that non-movant had not rebutted presumption of irreparable harm in light of finding that movant's market position would be threatened in the absence of injunctive relief).

If DexCom launches its infringing product before Abbott launches its product, the effect on Abbott's market share and product will be devastating and permanent. Even if the Court later awards Abbott patent infringement damages, Abbott

will not be made whole. It is well established in the medical device and pharmaceutical industries that the first company to launch an innovative product will generally capture a significant share of the market and retain substantial market share even after the subsequent launch of competing products. (Bratic Decl. at ¶ 11). This remains true even if subsequently launched products are higher quality or lower cost. (*Id.*).

These principles are particularly applicable to continuous glucose monitoring devices, because these products will so significantly change the way that patients manage and deal with diabetes. (Goodnow Decl. at ¶ 4). The first launcher will immediately capture a significant market share as patients who previously relied on finger-prick devices switch to the new technology. (Bratic Decl. at ¶ 11). Additionally, the first launcher will enjoy the benefits of having its product forever linked with life-changing technology, even after the launch of competing products that use similar and even improved technology. (*Id.*).

Recognizing these market dynamics, Abbott invested hundreds of millions of dollars to develop its technology and product. (Goodnow Decl. at ¶ 7). DexCom should not be permitted to reap the benefits of Abbott's enormous investment, particularly without giving Abbott the opportunity to make a preliminary showing that its patents are valid and DexCom's product would infringe them. Indeed, DexCom's attempt to piggy-back Abbott's technology is even more egregious because DexCom apparently changed its business plan to pursue short-term sensor technology only after learning about Abbott's ground-breaking work. (*See Id.* at ¶ 9).

DexCom's launch would not only result in DexCom permanently capturing a significant share of the market, it could also irreparably spoil the market.

(Bratic Decl. at ¶ 13). In the medical device and pharmaceutical industries, an innovative product that is ultimately proven unreliable can spoil the market for subsequent products using similar technology. (*Id.*). The problem is that consumers will equate the shortcomings of the initial product with shortcomings in the technology generally. (*Id.* at ¶¶ 13-14). This is true even if subsequent products use improved technology, because market perception of the product category will remain tainted. (*Id.*).

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Moreover, the fact that DexCom is seeking adjunct approval instead of replacement approval also threatens to spoil the market. (Goodnow Decl. at ¶¶ 13-14). In the context of glucose monitoring, adjunct approval means that the medical device has not gone through sufficiently rigorous clinical studies that the FDA feels comfortable allowing it to be used alone to test for glucose levels. (Goodnow Decl. at ¶ 11). Instead,

the FDA requires that patients using DexCom's device will also have to use finger-sticking, the current most common monitoring method. (*Id.*). The distinction between devices approved or not approved to replace traditional finger-stick therapy is significant. If patients are told they cannot rely on continuous monitoring systems, patients may think that the method is inadequate, thereby tainting the technology as inferior. (Goodnow Decl. at ¶ 13; Bratic Decl. at ¶ 13). Again, even after Abbott launches a product that is approved as a replacement for finger prick systems, Abbott would be required to expend millions of marketing dollars to educate the market, and these efforts might never be entirely successful. (Goodnow Decl. at ¶ 14).

Delaying Abbott's enforcement of its right to exclude until the conclusion of the reexamination could also be the practical equivalent of affording Abbott no patent protection at all. Courts have found irreparable injury when the technology in a certain field quickly changes because by the time the litigation is finished, it is entirely possible that the value of the patent will be diminished. *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1458 (Fed. Cir. 1988). As demonstrated by the PTO data DexCom attached to its brief, the average reexamination takes more than 21 months. If this litigation is delayed for nearly two years, DexCom may be able to capture nearly the entire lifespan of this technology. Two years from now, the market may have changed dramatically, and Abbott's patented technology may be far less valuable. Abbott should not be summarily denied its right to enforce its patents during this crucial time period without even the opportunity for a preliminary injunction hearing.

B. DexCom Is Seeking A Stay As A Tactical Maneuver

In addition to the undue prejudice in the marketplace of allowing DexCom to launch its infringing product, Abbott will suffer a closely related "clear tactical disadvantage" based on the simple fact that Abbott would lose the opportunity to be heard on its preliminary injunction motion. "Generally, courts are reluctant to stay proceedings where a party is using the reexamination process merely as a dilatory tactic." *Remington Arms Co., Inc. v. Modern Muzzleloading, Inc*, 1998 WL 1037920, * 3 (M.D.N.C. December 17, 1998) (citing *Freeman v. Minnesota Mining and Mfg. Co.*, 661 F. Supp. 886, 887 (D. Del. 1987)).

Here, DexCom is doing just that. DexCom has waited over six months to move for a stay in this litigation. Now, it files its requests for reexamination and its motion to stay when approval for its product is likely in the next month or two. By moving the Court for a stay, DexCom is seeking to have Abbott's injunctive remedies stripped away before any hearing on the issue simply because there is some possibility, however remote, that the PTO may alter the scope of some asserted claims.

Granting a stay based solely on "prudential" concerns would also extinguish the presumption of validity enjoyed by Abbott's patents. DexCom's motion thus is an attempt to avoid showing that its invalidity defense has substantial merit by clear and convincing evidence, which DexCom would be required to do at a preliminary injunction hearing. *See Oakley, Inc. v. Sunglass Hut Int'l.*, 316 F. 3d 1331, 1339 (Fed. Cir. 2003) (affirming grant of preliminary injunction in face of invalidity arguments). If DexCom fails and Abbott establishes its right for a preliminary injunction, DexCom cannot launch its product. DexCom has offered no basis – and not a single supporting

case – for stripping Abbott of its fundamental right to enforce its patents and to seek injunctive relief under the patent laws.

DexCom's conduct in this case also makes it clear that it is using the reexamination process as a device to delay any assessment of the case's merits. DexCom's stay motion is part of a pattern of attempting to impede the progress of this case, including by filing a motion to dismiss Count II under Rule 12(b)(6) that admittedly disregards specific allegations in the complaint, engaging in self-help by unilaterally declining to respond to a notice for a deposition scheduled for February 21, 2006, declining to participate in the court-ordered Rule 26(f) scheduling conference between counsel, and initially insisting on delaying for a full 28-days a deposition that this Court had ordered to take place within the "spirit" of Abbott's request for a deposition within ten days.[6] (Ex. 1 at p. 29:10-24).

At the same time it is attempting to impede this case's progress, DexCom is being intentionally vague about its prospects for a near-immediate commercial launch. As detailed above, DexCom advised this Court that it was "r*ight in the middle* of the FDA process," that the "FDA situation is *essentially identical* to what it was when this case was filed" in August 2005, that there was a "*significant probability*" of a panel

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review that could delay DexCom's launch by as much as a year, and that there "remains a *material likelihood* that we will be asked to modify that product." (Ex. 1 at p. 26:13-20 (emphasis added)). Yet, only four days later during an earnings conference call, DexCom's CEO publicly stated that they "hope for a decision from the FDA regarding the approvability of our PMA for the STS by early Q2," *which is only weeks away in April 2006*. (Ex. 2 at p. 1).

Allowing DexCom to benefit from these tactics "would not promote the efficient and timely resolution of patent cases, but would invite parties to unilaterally derail timely patent case resolution by seeking reexamination." *Sovereign Software*, 356 F. Supp. 2d at 662-63. DexCom's conduct in this case argues strongly in favor of denying DexCom's request for a stay.

II. A STAY WOULD DRAMATICALLY ALTER THE STATUS QUO; IT WOULD NOT SIMPLIFY THE ISSUES

DexCom also fails on the second factor of the stay analysis because a stay will not simplify the issues. Rather, DexCom's plan to launch an infringing product first and deal with the consequences later is laying the foundation for years of protracted litigation on issues of infringement, validity, and damages.

Indeed, the only way such protracted litigation could be avoided would be if the reexamination resulted in the PTO invalidating *all* of the asserted claims of *all* of the patents in suit, as well as any *additional* patent claims Abbott may assert later in this litigation. Such an outcome is entirely remote, as even DexCom would be required to concede based on the reexamination statistics it attached to its motion, which show that only 10% of reexaminations result in the cancellation of all claims. (*See* Ex. F to DexCom's Opening Brief). The alternative is far simpler – the Court should deny

DexCom's motion to stay and allow this case to proceed at least to the preliminary injunction phase, and then reconsider whether it makes any sense to stay the case after the resolution of that issue.

Other details make it even more clear that DexCom's reexamination petition is highly unlikely to narrow or simplify the issues. First, the PTO has not yet decided whether to accept two of DexCom's four reexamination requests. Second, Abbott has additional patents that it has not yet asserted, but will almost surely be added to the case in short order after further due diligence. Because these patents cover the same general subject matter, it does not make sense to cease discovery since it will have to occur with the non-reexamined patents. *See, e.g., Sovereign Software LLC*, 356 F. Supp. 2d at 662-63, (holding that the interests of justice would be better served by not staying the case and dealing with the contingency that some or all of the claims of the patents in suit will be affected by reexamination if and when that occurs).

Finally, DexCom's reexamination requests are insubstantial on their face. Although the Court does not need to evaluate the merits of those requests to deny the stay motion, DexCom is clearly using the reexamination process to unilaterally derail, rather than simplify, this litigation. As detailed above, DexCom is doing the bare minimum to trigger a reexamination under the low standard for doing so by, for instance, making garden-variety obviousness arguments for many claims, relying on a great deal of prior art that the PTO already examined, relying on a new art that plainly lacks key claim limitations, and arguing for claim interpretations it acknowledges would not be adopted by a court.

Under these circumstances, it is highly unlikely that DexCom's reexamination requests will meaningfully narrow or simplify the issues in this case. Thus, this factor weighs against a stay.

III. THE STAGE OF THE LITIGATION FAVORS ABBOTT IN LIGHT OF DEXCOM'S IMMINENT LAUNCH

In considering a party's request for a stay, courts also consider the stage of the proceedings. Here, the stage of the proceedings is particularly relevant and strongly supports denying the stay, because DexCom is preparing to launch immediately upon FDA approval, which could happen as early as a few weeks, and Abbott intends to oppose this launch by seeking an injunction. Staying the case at this stage of the proceedings thus would be grossly premature and would dramatically alter the status quo.

Courts have denied a stay where an injunction was sought. For instance, the Northern District of Illinois denied a motion to stay pending reexamination under such circumstances:

> According to the PTO, the average pendency of a reexamination is approximately 20 months. Such a long delay is important, in part, because [patentee] has filed a motion for a preliminary injunction. While it is unclear whether [patentee] will ultimately prevail in this motion, it is certain that if [patentee] has a good case and a long stay is granted, [patentee] will suffer great harm as [alleged infringer] infringes [patentee's] patent throughout the stay period and potentially reaps profits rightfully belonging to [patentee].

Amphenol T&M Antennas Inc. v. Centurion Intl. Inc., No. 00-C-4298, 2001 U.S. Dist. LEXIS 13795, at *7 (N.D. Ill. Sept. 5, 2001). Similarly, in *Remington Arms*, a stay was denied where "a stay for reexamination could last for years after such a passage of time, [patentee's] prayer for relief to enjoin [alleged infringer] from further infringement may

no longer have value as technology or market conditions change." *Remington Arms Co. v. Modern Muzzleloading Inc.*, No. 2:97CV00660, 1998 WL 1037920, at *2 (M.D.N.C. Dec. 17, 1998). S*ee also, Nexmed Holdings Inc. v. Block Inv. Inc.*, No. 2:04-CV-288 TS, 2006 U.S. Dist. LEXIS 3150, at *6 (D. Utah Jan. 19, 2006) (denying stay where "[p]laintiff faces the possibility that it may continue to be harmed by Defendant's alleged infringing actions").

Although courts also look at the stage of discovery and whether a trial date has been set, the court has put less weight into that factor when a party has used a jurisdictional issue to delay the case. *See, e.g., Centillion Data Systems, LLC v. Convergys Corp.*, No. 04-CV-0073, 2005 WL 2045786, at *1 (S.D. Ind. August 25, 2005) (noting that the "cause has been delayed for 18 months because [] defendants fought jurisdiction."). This is precisely the situation here. DexCom filed a motion to dismiss – which in Abbott's view is without merit – claiming a lack of subject matter jurisdiction and a failure to state a claim, and then unilaterally refusing to perform its discovery obligations.

The present case is not remotely similar to any of the cases DexCom relies on to support its request for a stay. In fact, DexCom did not cite a single case where the grant of a stay stripped the patentee of its right to seek injunctive relief before a product launch. *See, e.g.,. Tap Pharma Prods. v. Atrix Labs*, 70 U.S.P.Q. 2d 1319 (N.D. Ill. 2004) (court granted stay, on ground that the patent would expire before the end of the litigation anyway, and the accused product was already on the market and had been for some time, so there was no prejudice); *Patlex Corp. v. Mossinghoff*, 758 F.2d 594 (Fed. Cir. 1985) (instead of having anything to do with courts' granting or denying stays,

appellants challenged certain provisions of the patent reexamination statutes and their effect on the due process clause of the U.S. Constitution); *Ethicon, Inc. v. Quigg*, 849 F.2d 1422 (Fed. Cir. 1988) (case deals with the PTO staying reexamination hearings rather than courts staying patent infringement actions); *Robert H. Harris Co. v. Metal Mfg. Co.*, No. J-C-90-179, 1991 U.S. Dist. LEXIS 16086 (E.D. Ark. June 20, 1991) (in a case where a preliminary injunction was not sought, the court granted the stay because it found that plaintiff had an adequate legal remedy); *Whatley v. Nike, Inc.*, 54 U.S.P.Q.2d 1124 (D. Or. 2000) (court denying plaintiff's request for a stay because plaintiff refused to toll damages during pendency of reexamination proceedings).

Here, Abbott will be seeking injunctive relief to prevent DexCom's infringing product from launching when it receives FDA approval. The patents at issue have substantial remaining life, and Abbott would be irreparably harmed if DexCom is allowed to summarily strip Abbott of its right to enforce its patents without even giving Abbott the right to a preliminary injunction hearing.

CONCLUSION

For the foregoing reasons, Abbott respectfully requests this Court Deny DexCom's Motion To Stay Pending Reexamination of the Patents In Suit.

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March 10, 2006

CERTIFICATE OF SERVICE

I hereby certify that on March 22, 2006, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

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